# LGC launches unmethylated, methylated ctDNA mutation mixes

written by CAP TODAY
December 27, 2023

December 2023—LGC Clinical Diagnostics has launched Seraseq unmethylated and methylated ctDNA mutation mixes for assay development, validation, and routine performance monitoring. Key features of the products include global methylation of CpG sites to support all CpG methylation assays and enzymatically fragmented ctDNA for low background noise and physiologically relevant fragment sizes. Methylation status is quantified using digital PCR assays and validated by targeted next-generation sequencing panels. The products are manufactured in GMP-compliant, ISO 13485-certified facilities.




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# Mayo, Progentec to market biomarker tests for autoimmune diseases

written by CAP TODAY
December 27, 2023

December 2023—Mayo Clinic Laboratories announced a strategic collaboration to bring Progentec's proprietary biomarker blood tests for the management of autoimmune diseases to market. The collaboration aims to increase accessibility for providers and patients across the United States and select global markets.

# Cardiac Advance now compatible with Beckman instruments

written by CAP TODAY
December 27, 2023

December 2023—Bio-Rad Laboratories has announced the expanded compatibility of its cardiac control, Cardiac Advance, to include Beckman Coulter instruments. The next-generation control is optimized with troponin I and troponin T targets near the limit of instrument detection and contains 10 of the most tested cardiac analytes, including troponin, CK-MB, BNP/proBNP, and myoglobin. Cardiac Advance is available in multiple formats, including the Liquicheck and InteliQ human serum-based controls.




# OGT, Intelliseq partner to advance clinical insight from NGS data

written by CAP TODAY
December 27, 2023

December 2023—OGT announced a partnership with Intelliseq, a genome informatics company and provider of next-generation sequencing analysis solutions. The collaboration combines OGT's SureSeq NGS portfolio with Intelliseq's iFlow engine, providing a sample-to-report workflow. Users will be able to easily interpret variant calls made by OGT's NGS software via the Intelliseq iFlow engine.

# BD launches next-gen blood draw technology

written by CAP TODAY
December 27, 2023

December 2023—BD launched its FDA 510(k)–cleared Pivo Pro needle-free blood collection device, which is compatible with integrated and long peripheral IV catheters, including the Nexiva closed IV catheter system with NearPort IV Access. This expands current Pivo compatibility with short peripheral IV catheters.



# TriVerity gets FDA breakthrough device designation

written by CAP TODAY
December 27, 2023

December 2023—Inflammatix announced that the FDA has granted breakthrough device designation to its TriVerity acute infection and sepsis test system. The system, which is currently under development, includes the TriVerity test and Myrna instrument.

# FDA authorizes Invitae panel for common hereditary cancers

written by CAP TODAY
December 27, 2023

December 2023—The FDA has granted de novo marketing authorization for the Invitae Common Hereditary Cancers panel, an in vitro diagnostic test that can help detect hundreds of genetic variants associated with an elevated risk of developing certain cancers. The test can also help identify potentially cancer-associated hereditary variants in people who have an already-diagnosed cancer.



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# Quest, Scipher partner to expand testing for patients with RA

written by CAP TODAY
December 27, 2023

December 2023—Quest Diagnostics and Scipher Medicine announced a collaboration designed to expand patient access to diagnostic services for rheumatoid arthritis. Under a multiyear collaboration, Quest will provide RNA extraction and next-generation sequencing services for Scipher's PrismRA test, a blood-based molecular signature response classifier aimed at predicting a patient's response to TNF inhibitor therapy. Quest will enable specimen collection at about 7,300 patient access points and more than 2,100 patient service center locations, as well as courier services that transport patient specimens between Quest and Scipher laboratories and provider sites.

# Veracyte announces IVD agreement with Illumina

written by CAP TODAY
December 27, 2023

December 2023—Veracyte has entered into a multiyear agreement with Illumina to develop and offer some of its high-performing molecular tests as decentralized in vitro diagnostic tests on Illumina's NextSeq 550D× next-generation sequencing instrument. The agreement is part of Veracyte's expanded, multiplatform IVD approach, which will also include qPCR.



# Revvity study shows value of NGS in newborn screening

written by CAP TODAY
December 27, 2023

December 2023—A recent study by Revvity Omics has shown the clinical value of proactive, sequencing-based screening in apparently healthy newborns (Balciuniene J, et al. *JAMA Netw Open*. 2023;6[7]:e2326445). The objective of the study was to assess the clinical utility of genome sequencing versus a gene panel for a curated set of medically actionable pediatric-onset conditions in a large cohort of apparently healthy newborns and children tested at a clinical laboratory.